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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/872,156      | 06/04/2001  | Akira Tanaka         | 107380-00005        | 8786             |

7590 07/24/2003

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EXAMINER

HARTLEY, MICHAEL G

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1616

DATE MAILED: 07/24/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/872,156

Applicant(s)

TANAKA ET AL.

Examiner

Michael G. Hartley

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 June 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 2, 7 and 15-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-6 and 8-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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***Response to Arguments***

Applicant's arguments filed 06/3/2003 have been fully considered but they are not persuasive.

***Election/Restrictions***

Applicant asserts that the election was actually to Group III and that Group III should be combined with Group I since the restriction stated that the product would be combined with the method.

This is not found persuasive because the restriction requirement stated "Applicant's elect Group I" in the response to the restriction requirement. Thus, the product claims were examined. Also, the Group III claims (method of making) are only to be examined with the product if the method of making is not distinct from the product. However, the process of making the compounds in Group III is distinct, as such compounds may be made by materially different methods, such as, halogen exchange, tributyltin substitution etc. Since the product claims are not allowable at this time and Group III is drawn to a distinct method of making the compounds, Group III will only be rejoined at the time the product claims are allowable, (given the Group III claims are drawn to the same scope as the allowable product claims).

Applicant also asserts that the restriction was not made final.

This is not found persuasive as the election was made "without traverse."

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-6 and 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wester et al. (J Nucl. Med., 1999, PTO-1449) in view of Coenen (US 4,925,651) and Tomiyoshi (Nucl. Med. Comm., 1997, PTO-1449), for the reasons set forth in the office action mailed 1/10/2003.

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Applicant asserts that claimed provision of the methyl group at the 2 position and the positioning of the radiolabel in the species in claims 14 result in compounds that are quite different from the cited references.

This is not seen. The compound disclosed by Wester has the same position of the radiolabeled as claimed, (i.e. when R1 as claimed is phenyl). The compound disclosed by Wester is the same as that claimed (as applicant's elected species), except for the methyl group, i.e., Wester discloses radiolabeled tyrosine and radiolabeled methyl tyrosine is claimed. The position of the radiolabel in the compound disclosed by Wester corresponds to that of the claimed compound, as do the other chemical moieties present.

Applicant asserts that Coenen and Tomiyoshi teach a radiolabeling method using  $^{18}\text{F}_2$  gas which is an electrophilic method and that such a method would necessarily label  $^{18}\text{F}$  on the benzene ring and not the side chain. Thus, Coenen and Tomiyoshi do not render the claimed invention obvious.

This is not found persuasive because Coenen and Tomiyoshi are not relied upon for their teaching of methods of radiolabeling the compound as suggested by the above assertion. The compound disclosed by Wester is already radiolabeled at the same position as the claimed compound (applicant's elected species). Coenen and Tomiyoshi are relied upon for teaching the methyl tyrosine is equivalent to tyrosine as disclosed by Wester. As stated, the compound disclosed by Wester differs from the claimed compound only by the substitution of a methyl group for a hydrogen. Such substitution is known in the art to be a structurally obvious modification to gain the advantage of obtaining analogous chemically related compounds. For example, see *In re Wood*, 82 F.2d 638, 199 USPQ 137 (CCPA 1978). When compounds are so closely related that they are structurally obvious, an obviousness rejection may be made. However, Coenen and Tomiyoshi were cited as additional evidence to teach tyrosine and/or methyl tyrosine compounds are equivalents useful in PET imaging, but not to teach a method of radiolabeling, as the compound of Wester is already radiolabeled.

Applicant asserts that the compound disclosed by Wester is obtained by a nucleophilic method which is very complex, while the present invention uses a process which is simple.

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This is not found persuasive because the rejected claims are drawn to compounds and not the methods of making. It is accepted that a materially different process may be used to make such compounds, which is the reason that the product and process of making were restricted into different groups.

**Conclusion**

No claims are allowed at this time.

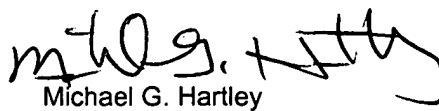
**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
Michael G. Hartley  
Primary Examiner  
Art Unit 1616

MH  
July 22, 2003